

y-MCLs

DRAFT: April 4, 1989

Proposals for the Imposition of  
Maximum Constituent Levels

Executive Summary

During the last 20 years, consumer preferences throughout the world have led gradually to increased sales of cigarettes with lower "tar" and nicotine ratings. Despite this, there have been calls from time to time for government regulation of maximum constituent levels ("MCLs"), which would mandate lower levels for these substances for all cigarettes. Yet the fact is that efforts to establish MCLs and thereby to force consumers to change their purchasing decisions are unlikely to improve public health. For this reason as well as others discussed below, calls for MCLs should continue to be rejected.

At the outset, it is important to recognize that the relationship between health and "tar" and nicotine levels remains unproven. In part, this is because the establishment of maximum "tar" ratings is an artificial process. Unlike constituents such as nicotine, "tar" is not a natural substance found in or given off by cigarettes. Instead, it consists of matter that is artificially taken from tobacco smoke by a machine in a laboratory. Machine-generated "tar" ratings do not translate directly into any measure of the "tar" received by individuals, and it therefore cannot be assumed that a reduction in "tar" levels will cause any changes in human health. Similarly, the health effects of nicotine, if any, are unproven. The U.S.

2025822363

- 2 -

Surgeon General has recognized that there is no definitive evidence that nicotine causes illnesses in humans.

Reflecting these facts, the scientific case in favor of MCLs remains uncertain at best. As a committee of the U.S. National Academy of Sciences concluded in 1982, overall "the evidence for switching to lower T/N ["tar"/nicotine] cigarettes is doubtful\* \* \* [W]hile some large-scale studies have suggested small gains in health due to lower T/N (or filter rather than nonfilter) cigarettes, other population-wide studies do not support this view."<sup>1</sup>

The dim prospects for health improvements from MCLs are further confirmed by the likelihood of compensatory smoking. Numerous studies have shown that many smokers forced to switch to lower-"tar" cigarettes will alter their smoking behavior so as to increase their consumption of "tar" and nicotine. These studies prompted the U.S. Surgeon General to conclude in 1982 that, "[s]mokers may increase the number of cigarettes they smoke and inhale more deeply when they switch to lower yield cigarettes. Compensatory behavior may negate any advantage of the lower yield product or even increase the health risk."<sup>2</sup>

These facts underscore the weak scientific basis for the establishment of MCLs. Moreover, experience has confirmed the desirability of allowing informed consumers to decide for themselves whether to smoke lower-yield cigarettes. Over the last two decades, reliance on free consumer choices has gradually led to substantial reductions in the "tar" and nicotine ratings of cigarettes. The

2025822364

- 3 -

imposition of government restrictions now would be unjustified and probably ineffective.

#### Discussion

During the last 20 years, consumer preferences throughout the world have led gradually to increased sales of cigarettes with lower "tar" and nicotine ratings. In 1970, for example, it was not uncommon for smokers to purchase cigarettes having a "tar" rating above 30mg. Now almost all cigarettes are well below that level. Indeed, it was only in 1979 that the first cigarettes with "tar" ratings below 10 mg were introduced in many European countries. By 1985, such cigarettes accounted for almost half of the total cigarettes sold in Europe.

The same trends also have been present in other part of the world. Throughout Asia, in countries such as South Korea, Japan and Hong Kong, filtered cigarettes now account for over 95 percent of all cigarettes sold.<sup>3</sup> Similarly, in Middle Eastern and South Asian countries the market share of filtered cigarettes has risen sharply.<sup>4</sup> For example, in Pakistan, the share of such cigarettes rose from 22 percent to 80 percent in only seven years.<sup>5</sup>

Despite these worldwide trends, there have been calls from time-to-time for government-mandated requirements for maximum constituent levels to require that all the "tar" and nicotine ratings of all cigarettes be within or below some arbitrary limit. Close scrutiny generally has shown that such regulations were unwarranted, and the

2025822365

- 4 -

call for them therefore has typically been abandoned.

Now, however, individuals in some countries have raised this issue yet again.

This paper first describes the characteristics of so-called lower-yield cigarettes -- cigarettes having machine-generated "tar" and nicotine ratings below a specified ceiling. It then reviews the state of scientific research on the health effects of lower-yield cigarettes, showing that scientists have not found any significant link between reductions in "tar" and nicotine and improvements in public health.

This paper next addresses the important but often overlooked effects of the individualistic nature of smokers and smoking. Studies have shown that if governments mandate reduced "tar" and nicotine ratings, some smokers may respond by smoking more or by otherwise altering their smoking practices to increase their consumption of those substances. As a result, lower-yield cigarettes might lead either to no reduction or possibly even to an increase in "tar" and nicotine consumption -- a result that MCL advocates are unlikely to favor. For all of these reasons, this paper concludes that government-mandated maximum constituent levels are not desirable and should -- as they have in the past -- be rejected by thoughtful decision-makers.

2025822366

#### I. The Characteristics of Lower-Yield Cigarettes

Despite the extended debate on maximum constituent levels, the basic characteristics of lower-yield

- 5 -

cigarettes are often forgotten. Yet these characteristics are critical to any consideration of the public health implications of such cigarettes. This is in part because, as described below, the "tar" rating of a cigarette does not necessarily reflect the amount of constituents actually inhaled by smokers. As a result, reductions in "tar" and nicotine ratings do not necessarily translate into different levels of smoker exposure to those substances.

The establishment of "tar" ratings is in many respects an artificial process. Unlike constituents such as nicotine, "tar" is not a natural substance found in or given off by cigarettes. Instead, "tar" is collected by drawing smoke from a cigarette into a smoking machine, which operates using a standardized puff volume, puff interval, puff length and stub length. The machine passes the smoke through a device that collects most of the particulate matter and then weighs and extracts the matter into a solution to determine its moisture and alkaloid content. This matter is arbitrarily labeled "tar" regardless of its actual composition.

The artificiality of this process has several important implications. First, machine-measured "tar" levels do not translate directly into any measure of the "tar" received by individuals. Individuals almost never smoke at the standardized puff volume, puff interval and puff length established by a machine. Critically, as discussed in detail below, the use of low "tar" and nicotine cigarettes may even alter individual smoking patterns -- a factor that must be taken into account when assessing the real-world

2025822367

- 6 -

effects of government efforts to regulate cigarettes depending upon their "tar" and nicotine ratings.

In addition, because matter is arbitrarily labeled as "tar" regardless of its actual composition, this short-hand expression encompasses a wide variety of substances. Indeed, even the weight of the matter collected from cigarettes of the same brand may vary somewhat because of differences between lots of tobacco, between smoking machines, and between human machine operators, all of which cannot be controlled precisely.

Given these facts, it cannot be assumed that a reduction in "tar" ratings will lead to improvements in public health -- even if one assumes, contrary to the views of many eminent scientists, that the amount of "tar" to which an individual smoker is exposed can lead to differential health effects. Such an improvement -- if it were to exist -- would be dependent on, first, the scientifically-established effects of "tar" and nicotine on the human body and, second, the smoking patterns of individuals who switched from regular to lower-yield cigarettes. As shown in the following two sections, neither indicator offers any genuine reason to believe that government-mandated lower-yield cigarettes would lead to improvements in public health.

2025822368

### III. Scientific Research on the Health Effects of Lower-Yield Cigarettes

Despite extensive research and experimentation, the scientific case for health improvements resulting from

- 7 -

lower-yield cigarettes remains uncertain at best. Scientific studies to date have yielded conflicting results, with the balance of the evidence showing that it is highly doubtful that government-mandated MCLs would lead to any significant improvements in public health.

Studies on the health effects of lower-yield cigarettes have taken several forms. Epidemiological and animal studies have focused specifically on the role of "tar" and nicotine in causing disease, to help determine whether reductions in them could be expected to bring improvements in human health. Other scientists have used biochemical tests to determine whether lower-yield cigarettes lead to reduced amounts of nicotine and other chemicals in the human body. Finally, some scientists have used population and experimental studies to determine whether smokers of lower-yield cigarettes enjoy better health than smokers of other cigarettes. Despite these varied forms of research, however, scientists have been unable to establish any substantial link between lower-yield cigarettes and significant improvements in public health.

A. Studies on the Role of "Tar" and Nicotine in Causing Human Disease

Many of the earliest scientific studies of lower-yield cigarettes focused on the possible role of "tar" and nicotine in causing human disease. Scientists hypothesized that if "tar" and nicotine play a major role in causing such disorders as heart disease and lung cancer, then reductions in these elements might lead to improvements in

2025822369

- 8 -

public health. As shown below, however, two decades of epidemiological and animal research have failed to establish a substantial link between these substances and human disease.

Heart Disease. An early theory relevant to lower-yield cigarettes was that nicotine increases a smoker's risk of heart disease. To assess this theory, scientists used epidemiological studies to compare the health of smokers exposed to different levels of nicotine.

Two important studies in the past decade have assessed the correlation between nicotine consumption and the risk of heart disease. In a 1981 study, a research team led by a British scientist opposed to smoking studied nicotine levels in male nonsmokers and smokers of cigarettes only, cigars only, and pipes only.<sup>6</sup> The study compared the observed level of cotinine, a nicotine metabolite, with the observed rate of heart disease. The researchers found no correlation between the two, and concluded that "nicotine is unlikely to be the major cause of the excess coronary heart disease mortality in cigarette smokers."<sup>7</sup>

The study's publication caused a substantial public debate, leading the British team to repeat its experiments by measuring specifically for nicotine rather than cotinine. The results did not change, however, leading the researchers to conclude that "we can be reasonably confident that exposure to high systematic concentrations of nicotine is not a cause of \* \* \* [heart] disease."<sup>8</sup>

A 1983 study by other researchers tested a similar hypothesis, exploring the possibility of a link be-

2025822370

- 9 -

tween the risk of heart attacks and nicotine and carbon monoxide.<sup>9</sup> Like the British scientists, this research team found no connection between the risk of heart attack and the nicotine level of cigarettes.<sup>10</sup> Three years later, a Finnish professor who favored lower-yield cigarettes, Dr. Arja Rimpela, examined this 1983 research in a report he submitted in 1986 to the Finnish National Board of Health. In his so-called "Rimpela Report", he concluded that the 1983 study "was a thorough one based on the case-control method. Serious methodological sources of error are not probable. If the effect had been significant, it would most probably have been found."<sup>11</sup>

Other scientists have used animal testing to explore the possible effects of nicotine on heart disease. The results of such tests have varied widely, depending on -- among other things -- the degree to which they used realistic dosages of nicotine. As an American researcher put it, "[t]here have been some studies that have exhibited minor or questionable changes with the use of 600 or more cigarettes a day in man. This is such a large number that I think man would find it difficult to find the time to smoke them."<sup>12</sup>

In sharp contrast, a series of animal tests using realistic dosage levels have, according to one scientist, "lent no support to the suggestion that cigarette smoking increases the rate of development" of clogging of the arteries.<sup>13</sup> Other scientists have agreed, noting that animal studies using realistic dosage levels have "failed to ini-

2025822321

- 10 -

tiate, exacerbate, or otherwise influence" the process leading to clogging of arteries in test animals.<sup>14</sup>

Throughout the past decade, leading public health officials who have examined these studies have called for continued research, but have found no proof in the existing work that nicotine causes heart disease. In 1983, the U.S. Surgeon General devoted his annual report to heart disease and noted that "the evidence for and against a primary role for nicotine in the development or acceleration of atherosclerosis is not conclusive."<sup>15</sup> Similarly, Professor Rimpela's 1986 report concluded that "[t]o date there is no epidemiological proof that low-tar cigarettes containing less than 10 mg tar are less harmful than other cigarettes as far as cardiovascular disease is concerned."<sup>16</sup> In summary, as one scientist has observed, "[w]hile many studies have been done in this field, none have established nicotine as contributing to the causation, aggravation or precipitation of any cardiovascular disease."<sup>17</sup>

Lung Cancer. To date, research on the relation between "tar" and lung disease is even less conclusive than that on heart disease. While some population studies have found a link between lower-yield cigarettes and reduced health risks, these findings could, as one British researcher observed, "be accounted for by biases in the samples and the changes that have occurred over the years in the quality and carcinogenicity of tobacco tar, rather than by an assumed reduction in the quantity of tar intake."<sup>18</sup>

Scientists also have examined the risk of lung cancer by engaging in laboratory testing on animals. Al-

202582322

- 11 -

though some tests on animals have suggested a possible link between "tar" and lung cancer, other scientists contend that the relevance of these tests to human smokers is questionable at best.

In these animal studies, scientists typically paint "tar" on the shaved backs or ears of test animals. There are, however, numerous differences between animal skin-painting tests and human cigarette consumption that render extrapolations from one environment to the other virtually impossible. First, the "tar" concentrations used in animal tests typically have been much higher than those found in cigarette smoking, and to this extent the experimental conditions have been unrealistic. Moreover, scientists have applied "tar" to animal tissues that are substantially different from the human lung and that do not protect the animals from "tar" as effectively as the mucous blanket that coats the human lung's lining. Finally, the "tar" used in animal experiments is different from that present in cigarette smoke. This is because "tar" undergoes chemical changes while it is stored; by the time the "tar" is used in skin-painting experiments, it has different properties from those found immediately after its extraction from cigarette smoke.

For all of these reasons, reliable conclusions about human health cannot be founded on these animal experiments. As one scientist observed, such experiments have applied "the wrong material, in the wrong form, in the wrong concentration, to the wrong tissue of the wrong animal."<sup>19</sup> As another scientist concluded, "laboratory re-

2025822373

- 12 -

ports on 'tar' yields have not been established as significant to human health."<sup>20</sup>

B. Biochemical Testing of Lower-Yield Cigarettes

In part because of the absence of any clear relationship between lower-yield cigarettes and human diseases, some scientists have turned to biochemical tests to measure the amount of smoking-related chemicals in the human body. These tests examine the presence of smoke components or their metabolic products, comparing the amounts found in the human body for lower-yield cigarettes with the amounts found for other cigarettes. These studies have proved no more conclusive than the disease-related research described above.

Biochemical tests are riddled with too many uncertainties and problems to provide convincing evidence about the health effects of lower-yield cigarettes. The problems begin with the critical fact that most of the chemicals that can be traced in the body, such as carbon monoxide, are found only in the gas phase of cigarette smoke. These chemicals therefore do not bear any necessary quantitative relationship to the particulates in "tar" that would be regulated by MCL restrictions. Accordingly, scientific studies that have examined levels of carbon monoxide and other chemicals, such as carboxyhemoglobin, have not found any systematic or reliable differences associated with lower-yield cigarettes. As the Rimpela report acknowledged, the few studies that have purported to document such a disparity have been of dubious validity.<sup>21</sup>

202582234

- 13 -

Ultimately, nicotine is the only substance relevant to possible MCL regulations that can even roughly be followed in the human body. Nicotine is, however, difficult to follow reliably because it has a very short half-life and because there is a wide variation among individuals in the amount of nicotine absorbed by the body. Moreover, smokers vary widely in puff rates, depth of inhalation, and body metabolism, rendering surveys of individuals inapplicable to any broader population. Finally, as discussed below, many individuals may engage in compensatory smoking if there is a reduction in nicotine content.

Not surprisingly, scientists have been unable to establish a correlation between the nicotine level of a cigarette or the number of cigarettes smoked and smokers' actual nicotine intake. A few studies have suggested that exposure to nicotine may be reduced somewhat by the use of lower-nicotine cigarettes, but several others have found no such correlation. For example, researchers assessing the yield levels used by the U.S. Federal Trade Commission found that those standards were "poor predictors of relative intake of nicotine, carbon monoxide, or tar" and that "the considerable variation of individual smoking behavior suggests that precise numerical rankings of cigarettes are not justified."<sup>22</sup> Another study reached the same conclusion after analyzing the biochemical marker serum thiocyanate in nearly 2,600 adult smokers in the United States. The authors concluded that "we and others find their use [of lower-yield cigarettes] is not associated with substan-

2025822375

- 14 -

tially reduced smoke exposure, nor perhaps with reduced risks for several smoking related diseases \* \* \*.<sup>23</sup>

In sum, biochemical testing has failed to provide even minimally persuasive evidence that lower-yield cigarettes result in improvements in human health. Like studies of a possible relationship between "tar" and nicotine and specific diseases, they do not provide a health-related justification for MCL regulations.

c. Conclusions on the Effects of Lower-Yield Cigarettes on Human Health

Recognizing the inconclusiveness of the scientific evidence, public health officials have conceded that there is no basis in science for finding that lower-yield cigarettes result in improvements in human health. For example, in 1982 a committee convened by the U.S. National Academy of Sciences analyzed the data and concluded that "the evidence for switching to lower T/N cigarettes is doubtful."<sup>24</sup> The committee added that "while some large-scale studies have suggested small gains in health due to lower T/N (or filter rather than nonfilter) cigarettes, other population-wide studies do not support this view."<sup>25</sup>

The Surgeon General of the United States has twice in this decade acknowledged this same fact. The Surgeon General's 1981 Report focused exclusively on "the changing cigarette" and "the relative health effects of cigarettes with varying levels of 'tar' and nicotine \* \* \*.<sup>26</sup> According to the author of the Report's preface, U.S. public health officials gradually have assumed a "more cau-

2025822326

- 15 -

tious" attitude towards lower-yield cigarettes, and the 1981 review of data "suggests an even more cautious approach to the issue."<sup>27</sup> The Surgeon General has recently confirmed this view, concluding in his 1989 Report that "there is no clear evidence of substantial health benefits to consumers who switch to lower tar and nicotine cigarettes."<sup>28</sup>

### III. Smoking Behavior Related to Lower-Yield Cigarettes: Compensatory Smoking and Circumvention

Although the studies described above clearly indicate that there is no scientific basis for mandating lower-yield cigarettes, even they fail to take account of an important confirmatory fact. That is the possibility that smokers forced to switch to lower-yield cigarettes may alter their smoking behavior so as to increase their consumption of "tar" and nicotine. One important problem with much of the debate on lower-yield cigarettes is that governmental standards are based on smoking by machines. While such devices may be helpful in quantifying some differences between some cigarettes, human beings are immeasurably more diverse -- and infinitely more adept at altering their behavior.

Research on such changes in smoking patterns -- termed compensatory smoking -- began in the early 1970s. Studies found that smokers switching to lower-yield cigarettes often alter their smoking patterns to compensate for reductions in "tar" and nicotine.<sup>29</sup> Subsequent research has shown the variety of ways in which smoking pat-

2025822372

- 16 -

terns may change with a switch to lower-yield cigarettes. One way, for example, is simply for individuals to smoke more cigarettes. A 1980 study found that consumers smoked more cigarettes when they switched to lower-yield cigarettes.<sup>30</sup>

Other changes also may occur. For example, many studies have shown that lower-yield cigarettes are smoked with a shorter puff interval than medium-yield cigarettes, causing an increase in the total volume of smoke inhaled.<sup>31</sup> This finding is echoed in other studies, which have found that the puff volumes for lower-yield cigarettes exceed those for regular cigarettes.<sup>32</sup> Still other studies have shown that the smoke from ventilated filter cigarettes is more deeply inhaled than the smoke from non-ventilated filter cigarettes.<sup>33</sup>

Smokers also may alter the amount of smoke inhaled by the way they hold their cigarettes. Lower-yield cigarettes often contain ventilation holes that -- other things being equal -- would reduce the amount of "tar" inhaled by smokers. A Canadian researcher has found, however, that nearly half of the smokers in real life either intentionally or by mistake close these ventilation holes with their lips or fingers.<sup>34</sup> This increases the constituent matter inhaled by the smoker.

Plainly, not all smokers will respond in the same way, and the studies of such changes have not produced uniform results. The studies show, however, that a decrease in the "tar" and nicotine levels of cigarettes will not necessarily translate into a reduced level of particulates

202582233  
84

- 17 -

inhaled by smokers. According to the U.S. Surgeon General, writing in 1982, "[s]mokers may increase the number of cigarettes they smoke and inhale more deeply when they switch to lower yield cigarettes. Compensatory behavior may negate any advantage of the lower yield product or even increase the health risk."<sup>35</sup>

Even the 1986 Rimpela report reached the same conclusion. Professor Rimpela concluded that:

"medium-tar and regular cigarettes are not smoked as intensively and efficiently as low-tars. Thus the measured yields of various cigarettes are not commensurable, the yields reported for low-tar cigarettes being far too low. When in addition to this the smoke from low-tars is more deeply inhaled, and when it is also possible that the consumption of individual smokers increases, low-tar cigarettes give a much higher yield of harmful components than has been presumed."<sup>36</sup>

As this makes clear, even the inconclusive scientific case for lower-yield cigarettes is vastly overstated unless the possibility of compensatory smoking is taken into account.

Finally, some smokers may not be content simply to alter their smoking practices. At least some smokers almost certainly will circumvent any decision limiting the sale of medium-"tar" cigarettes. Such steps are easily taken. For example, smokers need only remove the filter from low "tar" filtered cigarettes. Alternatively, some smokers may switch to self-rolled cigarettes, or purchase the cigarettes they prefer from bootleggers. Such actions, particularly when combined with the compensatory smoking of other individuals, will undercut or even negate entirely any changes that might result from government-mandated lower-yield cigarettes.

2025822329

- 18 -

V. Conclusions: The Importance of Consumer Preferences

The phenomenon of compensatory smoking underscores a central fact -- smoking is a matter of individual choice and practice. Like all consumers, smokers will evaluate products for themselves and then purchase or produce what they want -- and nothing else.

During the last twenty years, the power of consumer preferences has altered substantially the nature of cigarette sales. Throughout the world, tobacco companies now offer consumers a large variety of choices among a wide array of regular and lower-yield cigarettes. Consumers have reviewed these choices and gradually have chosen on their own to purchase increasing shares of lower-yield cigarettes.

Proponents of maximum constituent levels now seek to accelerate this trend even further by restricting choices and forcing consumers to purchase only limited types of cigarettes. Experience has demonstrated, however, the futility of efforts to force consumers to purchase products they do not want. The "Premier" "smokeless" cigarette most recently illustrates this fact. There was hope in some quarters that high advertising budgets and large quantities of free samples could lead consumers to purchase the "Premier" cigarette. All too soon, however, consumers decided for themselves that they did not like the product, and it was withdrawn from the market.

2025822380

- 19 -

In the same manner, there is little reason to believe that maximum constituent levels would lead to improvements for the public. Although framed as a health issue, there is no convincing evidence that the imposition of government-mandated maximum constituent levels will result in any health benefits. The scientific case for such benefits is at best weak, with conflicting results and substantial evidence that substances such as nicotine are not responsible for increased dangers to public health. Far from positively affecting the health of consumers, compensatory smoking could easily negate any effect of such regulations, with smokers responding to lower-yield cigarettes by altering their smoking practices.

Rather than imposing unsupported requirements, governments should rely instead on the educated decisions of consumers in the marketplace to choose how and what they will smoke. This has already led to substantial reductions in the "tar" and nicotine ratings of cigarettes. The imposition of government restrictions now would be unjustified and ineffective.

2025822381

- 20 -

References

1. NAS, 1982, at 5.
2. Surgeon General 1981 (emphasis added).
3. The Maxwell Reports (1987).
4. Id.
5. Id.
6. Wald, et al., 1981.
7. Id. at 775.
8. Wald, et al. 1984, at 367.
9. Kaufman et al. 1983.
10. Id.
11. A. Rimpela, Cigarettes of Maximum 10 MG Tar Yield -- Health Hazards and Recommended Action: Expert Report to the Finnish National Board of Health 23 (1986).
12. Fisher, 1983, 407.
13. Hazelton, 1981, at 5-6.
14. Fisher, 1983, 407.
15. 1983 SGR at 50.
16. Rimpela at 24.
17. Hockett, 1976, 147.
18. Russell, Banbury, 1980, at 297.
19. Hockett, 1976, at 146.
20. Okun, 1976, at 154.
21. Id. at 30.
22. Gori and Lynch, 1985, at 314.
23. Folsom, 1984, at 567.
24. NAS, 1982, at 5.
25. Id.

2025822382

- 21 -

26. 1981 SGR, at v.
27. 1981 SGR, Richmond, v-vi.
28. 1989 SGR, at 486.
29. H. Ashton and D.W. Watson, "Puffing Frequency and Nicotine Intake in Cigarette Smokers," 3 Br. Med. J. 679-81 (1970); C.D. Frith, "The Effect of Varying the Nicotine Content of Cigarettes on Human Smoking Behavior," 19 Psychocharmacologia 188-92 (1971).
30. Stephney 1980.
31. Creighton and Lewis 1978a, Rawbone et al. 1978, Kozlowski 1982, Puustinen et al. 1986.
32. Kozlowski et al. 1982.
33. Wald et al., 1980.
34. Kozlowski et al., 1980 and 1982.
35. Surgeon General 1981.
36. Rimpela at 19-20.

2025822383